DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-15, 21, 22, and 25-39) in the reply filed on June 12, 2008 is acknowledged.

2. The traversal is on the ground(s) that: with respect to Groups I and II, the Office Action does not specifically state which group is the combination and which group is the subcombination, and that both groups require electronic circuitry and output electrodes. With respect to Groups I and III, the Office Action does not specifically state which group is the combination and which group is the subcombination, and that both groups require treatment molecules.

3. In the requirement for restriction, filed on May 12, 2008, Examiner's original rationale for restriction between Groups I-III was incorrect as the Examiner stated that restriction to one of the Invention Groups was required under 35 U.S.C. 121. Applicant's case is a 371 application; therefore, restriction practice under 35 U.S.C. 121 and 372 applies. However, under proper restriction practice for 371 applications, the claim groupings as Groups I-III are still correct:

> Restriction is required under 35 U.S.C. 121 and 372:
>
> This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
>
> In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted:

I. Group I, claim(s) 1-15, 21, 22, and 25-39, drawn to a dressing and a device for treating damaged tissue.

II. Group II, claim(s) 16-20, 23, and 24, drawn to a control unit.

III. Group III, claim(s) 40, 42, and 43, drawn to a gel.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all of Groups I-III is not novel. The common technical feature is "treating damaged tissue", which is found in Claude (US 4,982,742) (Abstract). Therefore, the common technical feature is not considered "special" because it does not define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

4. Also, Applicant's arguments with respect to Groups I and II and Groups I and III are not persuasive. With respect to Groups I and II, Applicant states that the Office Action does not specifically state which group is the combination and which group is the subcombination; however, such is not valid as Examiner indicated in the Restriction Requirement (Page 2, paragraph 2) that "Inventions I and II are related as combination and subcombination." Concerning the statement that both groups require electronic circuitry and output electrodes, both groups do not require electronic circuitry and output electrodes as the independent claims of Combination Group I (claims 1, 7, 21, 25, and 29) do not require the electronic circuitry and output electrodes, which are specific to the control unit of the independent claim of Subcombination Group II (claim 16).

With respect to Groups I and III, Applicant states that the Office Action does not specifically state which group is the combination and which group is the subcombination; however, such is not valid as Examiner indicated in the Restriction Requirement (Page 3, paragraph 3) that "Inventions I and III are related as combination and subcombination." Concerning the statement that both groups include treatment molecules, both groups do not require treatment molecules as the independent claims of Combination Group I (claims 1, 7, 21, 25, and 29) do not require the treatment molecules, which are specific to the gel of the independent claim of Subcombination Group III (claim 40).

5. Applicant's election without traverse of Species B (Figures 2A-2B) in the reply filed on June 12, 2008, is acknowledged.

6. Currently, based on the restriction and election of species requirements, claims 1-15, 21, 25-33, and 35-39 are under examination.

The requirement is still deemed proper and is therefore made FINAL.

Priority

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: UNITED KINGDOM 0322851.7, filed September 30, 2003.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 7 recites the limitation "the gel". There is insufficient antecedent basis for this limitation in the claim as "the gel" has not been previously introduced in the independent claim as an element of the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 7-11, 13, 21, 25-27, 29, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Millot et al et al (US 6,411,853).

In regards to claims 1-3, 7-11, 13, 21, 25-27, 29, 35, and 36, Millot et al et al teaches a device (Figures 1-7) comprising:

b. a dressing (flexible support [34]) (column 2, line 34)

c. a pair of electrodes (electrodes [2][3])(column 4, lines 41-43)

d. a conductive gel (hydrophile layer [8]) between the electrodes (column 2, lines 34-47)(column 3, lines 3-31)

e. a sensor (sub-circuit [15]) (column 5, lines 19-23)

f. a control unit (electric supply means [9]) (column 2, lines 48-54)(column 2, lines 58-65)(column 5, lines 19-37)

12. Claims 1-3, 21, 29, 30, 32, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Claude (US 4,982,742).

In regards to claims 1, 2, 3, 21, 29, and 35, Claude teaches a device (Figures 1-5, apparatus [10]) comprising:

a. a dressing (bandage base [14])

b. a pair of electrodes (electrode means [32][42])

c. a conductive gel between the electrodes (conductive gel [36])

d. a control unit (circuit strip [26] containing circuitry [28])(column 2, lines 26-29)(column 2, lines 42-46)(column 3, lines 46-57)(column 4, lines 22-45)

In regards to claim 30, Claude teaches that the alternating current is varied between 50 and 500 microamps (Abstract)(column 5, lines 3-6).

In regards to claim 32, Claude does not state that the time period between each variation of amplitude and/or frequency is 0.1s; however, since Claude teaches that the minimum frequency of the current applied is 10 hertz (Abstract)(column 5, lines 3-7), through a simple formula (time period = 1/frequency), it can be calculated that the time period is 0.1s.

In regards to claim 33, Claude teaches that the alternating current has a ramp waveform (Figure 5)(column 4, lines 53-58).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al, as applied to claim 1 above, and further in view of Scherson et al (US 5,855,570).

In regards to claim 4, Millot et al is silent about pockets in a surface of the dressing adapted to hold the gel. Scherson et al teaches a dressing (Figure 1) have pockets (separator [32]) in a surface of the dressing adapted to hold a gel (column 4, lines 9-12). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the dressing of Millot et al with pockets, as taught by Scherson et al, as the pockets will function as storage components to house the gel before the dressing is ready to be applied to the patient and the pockets will prevent premature release of the gel from the dressing before the dressing is ready to be applied to the patient.

In regards to claims 5 and 6, Millot is silent about whether the gel is a conductive hydropolymer containing oxygen treatment molecules. Scherson et al teaches a conductive hydropolymer gel (column 3, lines 48-50) that generates oxygen (column 4, lines 9-19). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a conductive hydropolymer gel, as taught by Scherson et al, in the dressing of Millot et al, since as the device is used, the gel will generate oxygen that can be used to treat wounds topically without incurring systemic toxic side effects associated with extreme amounts of oxygen, as may occur in connection with hyperbaric oxygen chamber techniques of the prior art (column 1, lines 7-14).

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al, as applied to claim 7 above, and further in view of Lee (US 6,162,460).

In regards to claim 12, Millot et al does not teach that the environmental parameter detected by the sensor is one of oxygen, pH, bacterial infection, or temperature level, as the sensor [15] of Millot et al is used to determine impedance (column 5, lines 19-23). Lee teaches a dressing (Figures 6-7, poultice [10b]) for tissue treatment which has a sensor [35] to measure body temperature (column 6, lines 61-66). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the sensor of Millot et al to measure body temperature, as taught by Lee, as the body temperature determined by the sensor will be able to transferred as a signal to the control unit of the dressing as a control to modify the amount of current applied to the treatment site (i.e. if the body temperature is too high, for example, such a signal would be sent to the control unit in order to reduce the amount of current applied to the treatment site, since the higher amount of current may be overheating the patient) (column 8, lines 1-12).

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al, as applied to claim 7 above.

In regards to claim 14, Millot et al is silent about whether each electrode [2][3] is formed of a plurality of electrodes. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute each one electrode of Millot et al with a plurality of electrodes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al, as applied to claim 7 above, and further in view of Yavnai (US 2003/0176825).

In regards to claim 15, Millot et al does not teach interlinked air pockets in a surface of the dressing with a valve used to supply air to the air pockets. Yavnai teaches a device [100] (Figure 1B) with pockets (inflatable volume, *not referenced*, defined by seams [106], edge strip [108], and materials [102][104]) that are inflated with air by a valve [118] (paragraphs [0088][0090]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the surface of the dressing of Millot et al with air pockets and a valve, as taught by Yavnai, as the inflation of the air pockets will enable the device to be tightened around an appendage in order to efficiently secure the device to the patient's body, and in the inflated state, the device will be more rigid enabling the device to redistribute loads about the appendage to lessen pressure upon the patient's body at the treatment site (Abstract).

18. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claude, as applied to claim 29 above.

In regards to claim 31, Claude teaches that the frequency of the alternating current is varied between 10 and 50 hertz (Abstract)(column 5, lines 3-7); however, claim 31 requires the current to be varied between 10 and 900 hertz. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to vary the current up to the maximum frequency of 900 hertz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

19. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al, as applied to claim 36 above, and further in view of Jacobsen (US 5,860,957).

In regards to claims 37 and 38, Millot et al does not teach that the control unit comprises an i/o port and a wireless transceiver in order to wirelessly connect an external device to the control unit. Jacobsen teaches a system (Figures 1-2) comprising a control unit (control pad [10]) and a dressing (drug delivery patch [20]), wherein a wireless transceiver (external host interface/wireless link [48]) allows an external device (computer, *not referenced*) to wireless connect to the control unit memory [52] for the transfer of data to and from the external device (column 7, lines 28-41). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the dressing device of Millot et al with the wireless transceiver interface of Jacobsen, as such will allow the external device (computer) to wirelessly update the program and modify the treatment regimen of the dressing device based on monitored patient parameters (column 7, lines 28-41).

20. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al and Jacobsen et al, as applied to claim 38 above, and further in view of Claude.

In regards to claim 39, in a modified device of Millot et al and Jacobsen, Millot et al does not teach a removable tab within the control unit that controls whether current is passed through the device. Claude teaches a device (Figure 3, apparatus [10]) wherein a removable tab (pull away tab [52]) is electro-mechanically connected between a power source [50] and a ground point on the control unit [28]. When the tab [52] is intact, the power source [50] is connected to

ground point and energization of the control unit [28] does not occur. Once the tab is removed, the electrical connection between the power source [50] to ground point is broken, and as result, the power source [50] drives the control unit [28] to generate current (column 3, lines 37-45). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a removable tab, as taught by Claude, into the control unit, of the modified device of Millot et al and Jacobsen, as the tab will allow for the control of current dissipation by the control unit through the device, and will prevent the accidental dissipation of current from the device before the device is ready to be used (column 3, lines 37-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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